The opinion in support of the decision being entered today was <u>not</u> written for publication and is not binding precedent of the Board.

# UNITED STATES PATENT AND TRADEMARK OFFICE

# BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte JAMES LARKINS

Appeal No. 2005-2266¹ Application No. 10/077,591

ON BRIEF

MAILED

AUG 3 1 2005

U.S. PATENT AND TRADEMARK OFFICE BOARD OF PATENT APPEALS AND INTERFERENCES

Before SCHEINER, ADAMS and GREEN, <u>Administrative Patent Judges</u>.

ADAMS, Administrative Patent <u>Judge</u>.

## **DECISION ON APPEAL**

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 3, 4, 6, 11, 15-20, and 24-31. The examiner has indicated that claims 1, 2, 5, 7-10, 12-14 and 21-23 are allowable. Answer, page 2.

<sup>&</sup>lt;sup>1</sup> This appeal is substantially similar to Appeal No. 2004-1503, Application No. 09/606,808; Appeal No. 2004-1506, Application No. 09/771,938; Appeal No. 2004-1968, Application No. 10/00,0311; Appeal No. 2004-2317, Application No. 09/771,938; Appeal No. 2004-2343, Application No. 09/772,520; and Appeal No. 2005-0396, Application No. 10/077,589, which all share the same assignee, Monsanto Company, the parent of wholly-owned subsidiary DeKalb Genetics Corporation. Decisions reversing the rejections of record were entered into the record of each of these cases on March 31, 2005.

Claims 3, 4, 6, 15, 16, 17, 27, 28, 30 and 31 are illustrative of the subject matter on appeal and are reproduced below. In addition, for convenience, we have reproduced allowable claims 2 and 5 below:

- A population of seed of the corn variety I450436, wherein a sample of the seed of the corn variety I450436 was deposited under ATCC Accession No. PTA-4495.
- 3. The population of seed of claim 2, further defined as an essentially homogeneous population of seed.
- 4. The population of seed of claim 2, further defined as essentially free from hybrid seed.
- 5. A corn plant produced by growing a seed of the corn variety I450436, wherein a sample of the seed of the corn variety I450436 was deposited under ATCC Accession No. PTA-4495.
- 6. The corn plant of claim 5, having<sup>[2]</sup>:
  - (a) an SSR profile in accordance with the profile shown in Table 5 [sic, Table 6]; or
    - (b) an isozyme typing profile in accordance with the profile shown in Table 6 [sic, Table 7].
- 15. A corn plant capable of expressing all the physiological and morphological characteristics of the corn variety I450436, wherein a sample of the seed of the corn variety I450436 was deposited under ATCC Accession No. PTA-4495.
- 16. The corn plant of claim 15, further comprising a nuclear or cytoplasmic gene conferring male sterility.
- 17. A tissue culture of regenerable cells of a plant of corn variety I450436, wherein the tissue is capable of regenerating plants capable of expressing all the physiological and morphological characteristics of the

<sup>&</sup>lt;sup>2</sup> We note, as does the examiner (Answer, page 3) that claims 6 and 11 appear to include a typographical error in reference to the SSR and Isozyme typing profiles. As the examiner points out (Answer, page 6), "Table 6 depicts SSR profiles, while Table 7 depicts isozyme profiles." IN this regard, we note the examiner's statement (Answer, page 7), "claims 6 and 11 have not been amended to correct the typographical errors concerning table numbers, as was done in copending appealed application Serial No. 10/077,589", the subject matter of Appeal No. 2005-0396. Therefore, prior to any further action on the merits, we encourage the examiner and appellant to clarify this issue on the record.

corn variety I450436, wherein a sample of the seed of the corn variety I450436 was deposited under ATCC Accession No. PTA-4495.

- 27. The corn plant of claim 5, further defined as having a genome comprising a single locus conversion.
- 28. The corn plant of claim 27, wherein the single locus was stably inserted into a corn genome by transformation.
- 30. The corn plant of claim 27, wherein the locus confers a trait selected from the group consisting of herbicide tolerance; insect resistance; resistance to bacterial, fungal, nematode or viral disease; yield enhancement; waxy starch; improved nutritional quality; enhanced yield stability; male sterility and restoration of male fertility.
- 31. A method of producing an inbred corn plant derived from the corn variety 1450436, the method comprising the steps of:
  - (a) preparing a progeny plant derived from the corn variety I450436 by crossing a plant of the corn variety I450436 with a second corn plant, wherein a sample of the seed of the corn variety I450436 was deposited under ATCC Accession No. PTA-4495;
  - (b) crossing the progeny plant with itself or a second plant to produce a seed of a progeny plant of a subsequent generation;
  - (c) growing a progeny plant of a subsequent generation from said seed and crossing the progeny plant of a subsequent generation with itself or a second plant;
  - (d) repeating steps (b) and (c) for an addition[al]<sup>[3]</sup> 3-10 generations to produce an inbred corn plant derived from the corn variety 1450436.

The references relied upon by the examiner are:

Hunsperger et al. (Hunsperger)

5,523,520

Jun. 4, 1996

Eshed et al. (Eshed), "Less-Than-Additive Epistatic Interactions of Quantitative Trait Loci in Tomato," <u>Genetics</u>, Vol. 143, pp. 1807-17 (1996)

Kraft et al. (Kraft), "Linkage Disequilibrium and Fingerprinting in Sugar Beet," Theoretical and Applied Genetics, Vol. 101, pp. 323-36 (2000)

\_

<sup>&</sup>lt;sup>3</sup> See Answer, page 3.

# **GROUNDS OF REJECTION**

Claim 3 stands rejected under 35 U.S.C. § 112, second paragraph as indefinite in the recitation of the phrase "an essentially homogeneous population of seed."

Claim 4 stands rejected under 35 U.S.C. § 112, second paragraph as indefinite in the recitation of the phrase "essentially free from hybrid seed."

Claims 6 and 11 stand rejected under 35 U.S.C. § 112, second paragraph as indefinite in the recitation of the phrase "in accordance with."

Claims 15, 17 and 20 stand rejected under 35 U.S.C. § 112, second paragraph as indefinite in the recitation of the phrase "capable of expressing."

Claim 16 and 27-30 stand rejected under 35 U.S.C. § 112, second paragraph as failing to limit the scope of the claims from which they depend.

Claim 28 stands rejected under 35 U.S.C. § 112, second paragraph as indefinite in the recitation of "the article 'a' in the recitation 'wherein the single locus was stably inserted into <u>a</u> corn genome."

Claim 29 stands rejected under 35 U.S.C. § 112, second paragraph as indefinite in the recitation of the phrase "locus is selected ... dominant allele and a recessive allele."

Claim 30 stands rejected under 35 U.S.C. § 112, second paragraph as indefinite in the recitation of the phrases "yield enhancement," "improved nutritional quality," and "enhanced yield stability."

Claims 16 and 24-31 stand rejected under the written description provision of 35 U.S.C. § 112, first paragraph.

Claims 16 and 24-31 stand rejected under the enablement provision of 35 U.S.C. § 112, first paragraph.

We reverse.

## **BACKGROUND**

The present "invention relates to inbred corn seed and plants of the variety designated I450436, and derivatives and tissue cultures thereof."

Specification, page 1. According to appellant (specification, page 27), "[a] description of the physiological and morphological characteristics of corn plant I450436 is presented in Table 3" of the specification, pages 27-29. On this record the examiner has indicated that claims drawn to plants, plant parts, and seed of the corn variety designated I450436 are allowable. See e.g., claims 1, 2, 5, 7-10, 12 and 13, and Answer, page 2, wherein the examiner states "[c]laims 1-2, 5, 7-10, 12 [and] 13 ... are allowed."

A second aspect of the present invention comprises hybrid plants and processes "for producing [first generation (F<sub>1</sub>) hybrid<sup>4</sup>] corn seeds or plants,

<sup>&</sup>lt;sup>4</sup> According to the specification (page 21), a F<sub>1</sub> hybrid is "[t]he first generation progeny of the cross of two plants." Therefore, as we understand this record as well as the language of the claims, claims 24 and 25 refer to F<sub>1</sub> hybrids. Accordingly, it appears that claim 26 fails to further limit claim 25 from which it depends. In this regard, we note that claims 24-26 of the instant application are substantially similar to claims 24-26 of Appeal No. 2004-1506. The only difference between the claims of the two Appeals is the corn variety claimed. During the oral hearing in Appeal No. 2004-1506, appellant confirmed that all claims drawn to hybrid plants or hybrid seeds (see e.g., claims 24 and 25 of Appeal No. 2004-1506) refer to F<sub>1</sub> hybrids. See n. 6 of the Decision in Appeal No. 2004-1506. In addition, since claims 24 and 25 are limited to F1 hybrids, during oral hearing in Appeal No. 2004-1506, appellant conceded that claim 16 on that record, which depended from and further limited claim 25 to a first generation (F1) hybrid corn plant was superfluous and confirmed during the February 10, 2005 oral hearing that it was appellant's intent to cancel claim 26. See bridging paragraph, pages 1-2, of the Decision in Appeal No. 2004-1506. See also, Appeal No. 2004-2317, wherein appellant's representative confirmed during the February 10, 2005 oral hearing that all claims drawn to hybrid plants or hybrid seeds (see e.g., claims 24 and 25) refer to F<sub>1</sub> hybrids. We encourage the examiner and appellant to work together to remedy this issue, prior to any further action on the merits.

which ... generally comprise crossing a first parent corn plant with a second parent corn plant, wherein at least one of the first or second parent corn plants is a plant of the variety designated I450436." Specification, pages 7-9. On this record the examiner has indicated that claims drawn to a process of producing corn seed wherein the process comprises crossing a first parent corn plant with a second parent corn plant are allowable. See e.g., claims 21-23 and Answer, page 2, wherein the examiner states claims "21-23 are allowed."

A third aspect of the present invention comprises single locus converted plants of the corn variety I450436. Specification, page 6. As appellant explains (specification, page 23, emphasis added), single locus converted (conversion) plants are those plants

which are developed by a plant breeding technique called backcrossing wherein <u>essentially all</u> of the desired morphological and physiological characteristics of an inbred are recovered in addition to the characteristics conferred by the single locus transferred into the inbred <u>via</u> the backcrossing technique. A single locus may comprise one gene, or in the case of transgenic plants, one or more transgenes integrated into the host genome at a single site (locus).

As appellant explains (specification, page 31):

Many single locus traits have been identified that are not regularly selected for in the development of a new inbred but that can be improved by backcrossing techniques. Single locus traits may or may not be transgenic; examples of these traits include, but are not limited to, male sterility, waxy starch, herbicide resistance, resistance for bacterial, fungal, or viral disease, insect resistance, male fertility, enhanced nutritional quality, industrial usage, yield stability, and yield enhancement. These genes are generally inherited through the nucleus, but may be inherited through the cytoplasm. Some known exceptions to this are genes for male sterility, some of which are inherited cytoplasmically, but still act as single locus traits.

A final aspect of the present invention is directed to a process of producing an inbred corn plant <u>derived</u> from a plant of the corn variety I450436.

See e.g., claim 31. According to appellant's specification (bridging paragraph, pages 10-11),

the present invention provides a method of producing an inbred corn plant derived from the corn variety 1450436, the method comprising the steps of: (a) preparing a progeny plant derived from corn variety 1450436, wherein said preparing comprises crossing a plant of the corn variety 1450436 with a second corn plant, and wherein a sample of the seed of corn variety 1450436 has been deposited under ATCC Accession No. ... [PTA-4495]; (b) crossing the progeny plant with itself or a second plant to produce a seed of a progeny plant of a subsequent generation; (c) growing a progeny plant of a subsequent generation from said seed of a progeny plant of a subsequent generation and crossing the progeny plant of a subsequent generation with itself or a second plant; and (d) repeating steps (c) and (d) for an addition 3-10 generations to produce an inbred corn plant derived from the corn variety 1450436. In the method, it may be desirable to select particular plants resulting from step (c) for continued crossing according to steps (b) and (c). By selecting plants having one or more desirable traits, an inbred corn plant derived from the corn variety 1450436 is obtained which possesses some of the desirable traits of corn variety 1450436 as well potentially other selected traits.

Therefore, as we understand this aspect of the claimed invention (e.g., claim 31), the intent is <u>not</u> to claim a specific inbred corn plant resulting from the claimed process. <u>See</u> claim 31. Instead, as we understand it, claim 31 is drawn to a process wherein an inbred corn plant is <u>derived</u> from the corn variety 1450436.

As appellant explains (specification, page 3),

The development of uniform corn plant hybrids requires the development of homozygous inbred plants, the crossing of these inbred plants, and the evaluation of the crosses. Pedigree breeding and recurrent selection are examples of breeding methods used to

develop inbred plants from breeding populations. Those breeding methods combine the genetic backgrounds from two or more inbred plants or various other broad-based sources into breeding pools from which new inbred plants are developed by selfing and selection of desired phenotypes. The new inbreds are crossed with other inbred plants and the hybrids from these crosses are evaluated to determine which of those have commercial potential.

We emphasize, that while "new inbreds" having commercial potential may result from the method set forth in claim 31, the claim does not encompass any specific plant that is produced as a result of the method. Rather the claim encompasses only a method of producing an inbred corn plant that is "derived" from the corn variety I450436. The examiner has indicated that a claim drawn to a corn plant of the corn variety I450436 is allowable. See e.g., claim 5, and Answer, page 2, wherein the examiner states that claim 5 is allowed.

Against this backdrop, we now consider the rejections of record.

## DISCUSSION

# <u>Definiteness</u>:

Claims 3, 4, 6, 11, 15-17, 20 and 27-30 stand rejected under 35 U.S.C. § 112, second paragraph.

#### Claim 3

Claim 3 depends from independent claim 2, and stands rejected under 35 U.S.C. § 112, second paragraph as indefinite in the recitation of the phrase "an essentially homogeneous population of seed...." Answer, bridging paragraph, pages 3-4. The examiner interprets claim 2 as drawn to "a homogeneous population of genetically identical inbred seed." Answer, page 4, emphasis

added. Accordingly, the examiner finds (<u>id.</u>), "the 'essentially homogeneous' language [(in claim 3)] ... to be superfluous."

However, as disclosed in appellant's specification (page 5),

[e]ssentially homogeneous populations of inbred seed are those that consist essentially of the particular inbred seed, and are generally free from substantial numbers of other seed, so that the inbred seed forms between about 90% and about 100% of the total seed, and preferably, between about 95% and about 100% of the total seed.

Accordingly, we disagree with the examiner's assertion (Answer, page 5) that claim 3 is unclear simply because it may contain seed other than the seed of the corn variety I450436. We remind the examiner that claim language must be analyzed "not in a vacuum, but always in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary skill in the pertinent art." In re Moore, 439 F.2d 1232, 1235, 169 USPQ 236, 238 (CCPA 1971). In our opinion, a person of ordinary skill in the art would recognize that an essentially homogeneous population of seed of the corn variety I450436 is a population of seed that is generally free from substantial numbers of other seed, e.g., wherein corn variety I450436 seed forms between about 90% and about 100% of the total seed in the population. <sup>5</sup>

Accordingly, we reverse the rejection of claim 3 under 35 U.S.C. § 112, second paragraph.

<sup>&</sup>lt;sup>5</sup> <u>Cf.</u> the examiner's statement (Answer, bridging sentence, pages 5-6), "amending claim 3 to read '[a]n essentially homogeneous population of corn seeds consisting essentially of seed of claim 1', would obviate this rejection."

Appeal No. 2005-2266 Application No. 10/077,591

## Claim 4

According to the examiner (Answer, page 4), claim 4 stands rejected under 35 U.S.C. § 112, second paragraph as indefinite in the recitation of the phrase "essentially free from hybrid seed," "for reasons similar to the rejection of claim 3. Thus, the examiner recommends (<u>id.</u>), claim 4 be amended to read, "[a] population of corn seeds consisting essentially of the inbred corn seed of claim 2, and essentially free from hybrid seeds." Therefore, for the reasons, set forth in our discussion of the rejection of claim 3 under 35 U.S.C. § 112, second paragraph above, we agree with appellant (Brief, page 6), claim 4 "adds an additional element [to claim 2] specifying that the population of seed is essentially free from hybrid seed."

Accordingly, we reverse the rejection of claim 4 under 35 U.S.C. § 112, second paragraph.

## Claim 14

Claim 14 stands rejected under 35 U.S.C. § 112, second paragraph as indefinite in the recitation of the phrase "[a]n essentially homogeneous population of corn plants produced by growing the seed of the corn variety I450436." Answer, page 6. According to the examiner (Answer, bridging paragraph, pages 6-7), "[t]he I450436 seed can only produce I450436 plants. ... [Therefore,] [t]he population can ... only consist of I450436 plants." Accordingly, the examiner finds it unclear "why the population is referred to as 'essentially

homogeneous,' since such populations can comprise more than one variety of plant." Answer, page 7.

As appellant discloses (specification, page 6), "[t]he population of inbred corn seed of the invention can further be particularly defined as being essentially free from hybrid seed. The inbred seed population may be separately grown to provide an essentially homogeneous population of inbred corn plants designated 1450436." As we understand the claim, growing the seed of claim 3, for example, would produce an essentially homogeneous population of corn plants of the corn variety 1450436.

In addition, we direct the examiner's attention to Appeal No. 2005-0396, wherein a claim similar to claim 14 was presented for our review. In Appeal No. 2005-0396, the examiner of record indicated that claim 14, directed to "[a]n essentially homogeneous population of corn plants produced by growing the seed of the corn variety I180580...." was allowable. Accordingly, we find that the examiner has treated claim 14 in a manner that is inconsistent with the prosecution of claim 14 in 2005-0396. As we understand it, the only difference between claim 14 as it appears in Appeal No. 2005-0396 and the instant appeal is the variety of corn seed from which the plant is produced.

Accordingly we reverse the rejection of claim 14 under 35 U.S.C. § 112, second paragraph.

<sup>&</sup>lt;sup>6</sup> <u>Cf</u>. The examiner's statement (Answer, page 8), amending claim 14 "to read, '[a]n essentially homogeneous population of corn plants produced by growing a population of corn seed consisting essentially of the seed of corn plant I450436...' would obviate the rejection."

## Claims 6 and 11

Claims 6 and 11 stand rejected under 35 U.S.C. § 112, second paragraph as indefinite in the recitation of the phrase "in accordance with." According to the examiner (Answer, page 7), "[i]t is not clear what is meant by a marker profile that 'agrees' with another marker profile. Are they the same or not?"

On this record, we understand the phrase "in accordance with" as it is used in claims 6 and 11 to mean "the same". Stated differently, we understand the claims to read:

- 6. The corn plant of claim 5, having:
  - (a) the same SSR profile as shown in Table 6; or
  - (b) the same isozyme typing profile as shown in Table 7.
- 11. The plant part of claim 10, wherein said cell is further defined as having:
  - (a) the same SSR profile as shown in Table 6; or
  - (b) the same isozyme typing profile as shown in Table 7.

Accordingly we reverse the rejection of claims 6 and 11 under 35 U.S.C. § 112, second paragraph.

# Claims 15 and 17-20

Claims 15, 17 and 20 stand rejected under 35 U.S.C. § 112, second paragraph as indefinite in the recitation of the phrase "capable of expressing," or "capable of regenerating." According to the examiner finds (Answer, page 8),

while the plant has the capacity to express the characteristics, for some reason it may not. Certain characteristics of a plant are expressed only at certain times of its life cycle, and are incapable

<sup>&</sup>lt;sup>7</sup> During the February 10, 2005 oral hearing of Appeal No. 2004-2317, appellant's representative confirmed that the phrase "in accordance with" was intended to mean "the same." We see no reason to treat this phrase differently on this record, wherein the specification and the claims are substantially similar to the specification and claims of Appeal No. 2004-2317.

of being expressed at other times. The colors of flower parts such as silks, or fruit parts such as husks, are examples. The promoters of many genes conferring traits require a transcription factor to become active. Is a plant that has such a gene, but not the transcription factor, considered "capable of expressing" that gene, and the trait associated with that gene, and is such a plant encompassed by the claims?

To address the examiner's concerns, we find it sufficient to state that if a plant has the capacity to express the claimed characteristics it meets the requirement of the claim regarding "capable of," notwithstanding that due to a particular phase of the life cycle the plant is not currently expressing a particular characteristic. Alternatively, if a plant is incapable of expressing the claimed characteristics at any phase of the life cycle, because it lacks, for example, the "transcription factor" required for expression – such a plant would not meet the requirement of the claim regarding "capable of."

Here, we find the examiner's extremely technical criticism to be a departure from the legally correct standard of considering the claimed invention from the perspective of one possessing ordinary skill in the art. <sup>8</sup> In our opinion, a person of ordinary skill in the art would understand what is claimed. Amgen Inc. v. Chugai Pharmaceutical Co., Ltd., 927 F.2d 1200, 1217, 18 USPQ2d 1016, 1030 (Fed. Cir. 1991). We find the same to be true for the phrase "capable of" as set forth in claims 17 and 20.

Accordingly we reverse the rejection of claims 15, and 17-20 under 35 U.S.C. § 112, second paragraph.

## Claims 16 and 27-30

Claims 16 and 27-30 stand rejected under 35 U.S.C. § 112, second paragraph as failing to limit the scope of the claims from which they depend. According to the examiner (Answer, page 9), since the plant set forth in claim 16 is male sterile it cannot express all the morphological and physiological characteristics of the male fertile corn variety I450436. Similarly, the examiner finds it unclear whether the plant set forth in claim 27 has all the characteristics of the plant set forth in claim 5, from which claim 27 depends. Answer, page 10. In response, appellant asserts (Brief, bridging paragraph, pages 7-8), claims 16 and 27-30 simply add a further limitation to the claims from which they depend. We agree.

For example, claim 16 reads on a corn plant capable of expressing all the physiological and morphological characteristics of the corn variety I450436, further comprising a nuclear or cytoplasmic gene conferring male sterility. In our opinion, the claims reasonably apprise those of skill in the art of their scope.

Amgen. As set forth in Shatterproof Glass Corp. v. Libbey-Owens Ford Co., 758

F.2d 613, 624, 225 USPQ 634, 641 (Fed. Cir. 1985), "[i]f the claims, read in the light of the specifications, reasonably apprise those skilled in the art both of the utilization and scope of the invention, and if the language is as precise as the subject matter permits, the courts can demand no more."

Accordingly we reverse the rejection of claims 16 and 27-30 under 35 U.S.C. § 112, second paragraph.

<sup>&</sup>lt;sup>8</sup> Cf. Digital Equipment Corp. v. Diamond, 653 F.2d 701, 724, 210 USPQ 521, 546 (CA 1981).

# Claim 28

Claim 28 stands rejected under 35 U.S.C. § 112, second paragraph as indefinite in the recitation of the article "a" in the recitation "wherein the single locus was stably inserted into a corn genome...." According to the examiner (Answer, page 11), the recitation does not make clear if the genome is that of 1450436 or that of a different corn plant.

According to appellant's specification (page 23, emphasis removed), a "Single Locus Converted (Conversion) Plant" refers to

[p]lants which are developed by a plant breeding technique called backcrossing wherein essentially all of the desired morphological and physiological characteristics of an inbred are recovered in addition to the characteristics conferred by the single locus transferred into the inbred <u>via</u> the backcrossing technique. A single locus may comprise one gene, or in the case of transgenic plants, one or more transgenes integrated into the host genome at a single site (locus).

Accordingly, we agree with appellant (Brief, page 8) "[t]he single locus referred to in claim 28 may or may not have been directly inserted into the genome of the claimed plant." As we understand the claim, and arguments of record, claim 28 presents two possibilities: (1) the single locus is directly inserted into the claimed plant and nothing further need be done; or (2) the single locus is directly inserted into a different plant, which is then used to transfer the single locus to the claimed plant through use of the plant breeding technique known as backcrossing.

Regarding the examiner concern (Answer, page 11) that "a locus is a position on a genome rather than a piece of DNA or a gene", we note that page

22 of appellant's specification states "[a] single locus may comprise one gene, or in the case of transgenic plants, one or more trangenes integrated into the host genome at a single site (locus)."

For the foregoing reasons, it is our opinion that the claim reasonably apprises those of skill in the art of its scope. <u>Amgen</u>. Accordingly, we reverse the rejection of claim 28 under 35 U.S.C. § 112, second paragraph.

# Claim 29

The examiner finds (Answer, page 8), claim 29 is indefinite in the recitation of a locus selected from the group consisting of a dominant allele and a recessive allele. According to the examiner (id.), "a locus is a location on a genome, and is not an allele." As appellant explains (Brief, page 9), page 22 of the specification discloses that "[a] single locus may comprise one gene, or in the case of transgenic plants, one or more transgenes integrated into the host genome at a single site (locus)." According to appellant (id.), "a single locus conversion refers to the gene introduced and not a locus on the chromosome. [Thus,] [t]here is nothing indefinite in the recitation of a single locus conversion that is a dominant allele or a recessive allele."

In response, the examiner finds (Answer, page 12), "[i]f claim 29 read, -the conversion—rather than 'the locus', [a]ppellant's arguments would be more
persuasive." Claim 29 depends from claim 27, which is drawn to "[t]he corn plant
of claim 5, further defined as having a genome comprising a single locus
conversion." In claim 29, appellant chose to refer to this "single locus

conversion" as "the locus." As we understand the rejection, the examiner prefers that appellant refer to the "single locus conversion" of claim 27 as "the conversion." We fail to see why referring to the "single locus conversion" of claim 27 as the "conversion" would be any clearer than appellant's use of the term "locus." In our opinion, the claim reasonably apprises those of skill in the art of its scope. Amgen. Accordingly, we reverse the rejection of claim 29 under 35 U.S.C. § 112, second paragraph.

# Claim 30

Claim 30 stands rejected under 35 U.S.C. § 112, second paragraph as indefinite in the recitation of the phrases "yield enhancement," "improved nutritional quality," and "enhanced yield stability." According to the examiner (Answer, page 13), the terms "yield enhancement," "improved nutritional quality," and "enhanced yield stability" are "relative terms which do not clearly specify the degree of trait expression." The examiner is correct (id.), when a word of degree is used appellant's specification must provide some standard for measuring that degree. Seattle Box. Co. v. Industrial Crating & Packing, Inc., 731 F.2d 818, 826, 221 USPQ 568, 573-574 (Fed. Cir. 1984).

<sup>&</sup>lt;sup>9</sup> To this end, we note that a similar claim was presented for our review in Appeal Nos. 2004-1506 and 2004-2317. See claim 29 presented for our review in each appeal. However, the examiner of record in Appeal Nos. 2004-1506 and 2004-2317 apparently found that a person of ordinary skill in the art would have understood the scope of the claim, as no comment was made on either of these records, to reflect that the language of claim 29 was indefinite with regard to appellant's use of the term "locus" in referring to "a single locus conversion," as is presented herein for our review.

On this record, appellant asserts (Brief, page 11), it is "understood the enhancement of yield or yield stability and improved nutritional quality is relative to a plant lacking the single locus. The metes and bounds of the claim are thus fully understood by one of skill in the art and the use of the terms is not indefinite." On reflection, we agree with appellant. The fact that some claim language is not mathematically precise does not per se render the claim indefinite. Seattle Box. As set forth in Shatterproof Glass, "[i]f the claims, read in the light of the specifications, reasonably apprise those skilled in the art both of the utilization and scope of the invention, and if the language is as precise as the subject matter permits, the courts can demand no more." In our opinion, a person of ordinary skill in the art would have understood the enhancement of yield or yield stability and improved nutritional quality is relative to a plant lacking the single locus.

Accordingly we reverse the rejection of claim 30 under 35 U.S.C. § 112, second paragraph.

# Written Description:

Claims 16, and 24-31 stand rejected under 35 U.S.C. § 112, first paragraph, as the specification fails to adequately describe the claimed invention. For the following reasons, we reverse.

Appeal No. 2005-2266 Application No. 10/077,591

## Claims 16 and 27-30

According to the examiner (Answer, page 14), the claims are drawn to 1450436 plants further comprising "any 'single locus conversion' of any sequence and from any source organism which confers any trait (claims 27-29) or which confers particular traits (claims 16 and 30)...." In this regard, the examiner recognizes that "[t]he specification contemplates numerous different single loci involved in expressing various traits...." Answer, page 17.

Nevertheless, the examiner finds (id.), "the specification does not describe a multitude of non-exemplified transgenes conferring a multitude of unspecified traits... with regard to sequence, source, or function...." More specifically, the examiner finds (Answer, page 18), "the genes for several of the contemplated traits; i.e., 'improved nutritional quality', 'yield enhancement' and 'enhanced yield stability' as recited in claim 30 ... have not been isolated either by [a]ppellant or by the skilled artisan."

The examiner, however, provides no evidence to support the assertion that a person of ordinary skill in the art would not recognize or know of genes useful to produce single locus conversions of the claimed corn plant, or more specifically that single loci for yield enhancement or yield stability are known in the art. In this regard, we note that appellant discloses (specification, page 31), "[m]any single locus traits have been identified ... examples of these traits include, but are not limited to, male sterility, ... enhanced nutritional quality, industrial usage, yield stability, and yield enhancement." It appears that the examiner has overlooked appellant's assertion that single locus traits for male

sterility, improved nutritional quality, yield stability and yield enhancement are well known in the art. To this end, we direct the examiner's attention to, for example, United States Patent No. 5,936,145 ('145)<sup>10</sup>, issued August 10, 1999, which is prior to the filing date of the instant application. For clarity, we reproduce claims 8, 29 and 39 of the '145 patent below:

- 8. A corn plant having all the physiological and morphological characteristics of corn plant 87DIA4, a sample of the seed of said corn plant having been deposited under ATCC Accession No. 203192.
- 29. The corn plant of claim 8, further comprising a single gene conversion.
- 39. The single gene conversion of the corn plant of claim 29, where the gene confers enhanced yield stability.

As we understand it, claim 39 of the '145 patent, is drawn to a corn plant which comprises a single gene conversion, wherein the gene confers enhanced yield stability. Thus, contrary to the examiner's assertion it appears, for example, that a single gene that confers enhanced yield stability was known in the art prior to the filing date of the instant application. We remind the examiner "a patent need not teach, and preferably omits, what is well known in the art."

Hybritech Incorporated v. Monoclonal Antibodies. Inc. 802 F.2d 1367, 1385, 231 USPQ 81, 94 (Fed. Cir. 1986). Further, to the extent that the examiner is asserting that appellant has not provided an enabling disclosure of single loci that have not been identified, we note that to satisfy the written description requirement, the inventor "must convey with reasonable clarity to those skilled in

<sup>&</sup>lt;sup>10</sup> We note that the assignee of the '145 patent is DeKalb Genetics Corporation. The assignee of the present application is Monsanto Company, the parent of wholly-owned subsidiary DeKalb Genetics Corporation.

the art that, <u>as of the filing date sought</u>, he or she was in possession of the invention" [emphasis added]. <u>Vas-Cath</u>.

We remind the examiner that the inquiry into whether the description requirement is met must be determined on a case-by-case basis and is a question of fact. Wertheim, 541 F.2d at 262, 191 USPQ at 96. A description as filled is presumed to be adequate; unless or until sufficient evidence or reasoning to the contrary has been presented by the examiner to rebut the presumption.

See e.g., Marzocchi. The examiner, therefore, must have a reasonable basis to challenge the adequacy of the written description. Accordingly, it is the examiner who has the initial burden of establishing by a preponderance of evidence that a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims. Wertheim, 541 F.2d at 263, 191 USPQ at 97. On this record, the examiner provides no evidence to support the assertion that single loci that govern, for example, yield enhancement or enhanced yield stability are not described.

For the foregoing reasons, we are not persuaded by the examiner's arguments. Accordingly, we reverse the rejection of claims 16 and 27-30 under the written description provision of 35 U.S.C. § 112, first paragraph.

## Claims 24-26

Claims 24-26 ultimately depend from claim 23, which the examiner has indicated is allowable. Answer, page 2. The examiner finds (Answer, page 16),

Appeal No. 2005-2266 Application No. 10/077,591

claims 24 and 25 are drawn to a hybrid plant or seed "produced by crossing inbred corn plant I450436 with any second, distinct inbred corn plant."

As we understand it, based on this construction of claims 24 and 25, the examiner is of the opinion that since the hybrids inherit only ½ of their diploid<sup>11</sup> set of chromosomes from the plant of corn variety I450436, a person of skill in the art would not have viewed the teachings of the specification as sufficient to demonstrate that appellant was in possession of the genus of hybrid seeds and plants encompassed by claims 24 and 25. According to the examiner (Answer, page 22), "[t]he fact that any hybrid plant will inherit half of its alleles from I450436 then does not provide sufficient description of the morphological and physiological characteristics expressed by the claimed hybrid plants."

There is no doubt that the expressed gene products of a hybrid plant, e.g., the morphological and physiological traits, of I450436 and a non-I450436 corn plant will depend on the combination of the genetic material inherited from both parents. See Answer, page 23. Nevertheless, we disagree with the examiner's conclusion (id.) that "[t]he fact that any hybrid plant will inherit half of its alleles from I450436 then does not provide sufficient description of the morphological and physiological characteristics expressed by the claimed hybrid plants."

On these facts, we find it necessary to take a step back and consider what is claimed. The claims are drawn to a F<sub>1</sub> hybrid seed (claim 24) or plant

<sup>&</sup>lt;sup>11</sup> According to appellant's specification (page 21), diploid means "a cell or organism having two sets of chromosomes."

(claim 25) resulting from a cross between a plant of corn variety I450436 and a non-I450436 corn variety. As discussed above (n. 4), as we understand the inventions of claim 24-26, claim 26 is redundant to claim 25. The claims do not require the hybrid to express any particular morphological or physiological characteristic. Nor do the claims require that a particular non-I450436 corn variety be used. If All that is required by the claims is that the hybrid has one parent that is a plant of corn variety I450436. Since the examiner has indicated that the seed and the plant of the corn variety I450436 are allowable (see claims 1 and 5), there can be no doubt that the specification provides an adequate written description of this corn variety. In addition, appellant's specification describes an exemplary hybrid wherein one parent was a plant of the corn variety I450436, see e.g., specification, pages 53-59. Accordingly, it is unclear to this merits panel what additional description is necessary.

As set forth in Reiffin v. Microsoft Corp., 214 F.3d 1342, 1345, 54
USPQ2d 1915, 1917 (Fed. Cir. 2000), the purpose of the written description
requirement is to "ensure that the scope of the right to exclude, as set forth in
the claims does not overreach the scope of the inventor's contribution to the field
of art as described in the patent specification." Here the hybrid seed or plant
has one parent that is a plant of the corn variety I450436. To that end, to satisfy
the written description requirement, the inventor "must convey with reasonable
clarity to those skilled in the art that, as of the filing date sought, he or she was

<sup>&</sup>lt;sup>12</sup> According to appellant (Brief, page 15), "hundreds or even thousands of different inbred corn lines were well known to those of skill in the art prior to the filing [date] of the instant application, each of which could be crossed to make a hybrid plant with in the scope of the claims."

in possession of the invention" [emphasis added]. <u>Vas-Cath Inc. v. Mahurkar</u>, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). For the foregoing reasons it is our opinion that appellant has provided an adequate written description of the subject matter set forth in claims 24 and 25.

# Claim 31

Claim 31 is drawn to a method of producing an inbred corn plant derived from the corn variety I450436. The claimed method begins by crossing a plant of the corn variety I450436 with any other corn plant. The method requires that the progeny corn plant be crossed either to itself, or with any other corn plant, and that the progeny of this cross be further crossed to itself, or with another corn plant, and so on throughout several generations. As we understand it, claim 31, in its simplest form, is directed to a method of using a plant of the corn variety I450436 to produce an inbred corn plant.

As set forth in Reiffin, the purpose of the written description requirement is to "ensure that the scope of the right to exclude, as set forth in the claims does not overreach the scope of the inventor's contribution to the field of art as described in the patent specification." Here the method of producing an inbred corn plant requires a plant of the corn variety I450436 be used as the starting material. To that end, to satisfy the written description requirement, the inventor "must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention" [emphasis added]. Vas-Cath. The examiner has indicated that a claim to a plant of the

corn variety I450436 is allowable, <u>see e.g.</u>, appellant's claim 5. Therefore, in our opinion, there can be no doubt that appellant was in possession of a plant of the corn variety I450436, in addition to a method of using that plant to cross with any other corn plant to produce an inbred corn plant as set forth in appellant's claim 31.

In our opinion, and contrary to the examiner's assertions (Answer, pages 19-23), it matters not what the other corn plants are, or what the progeny of a cross between corn variety I450436 and some other corn plant represents. Accordingly, for the foregoing reasons, it is our opinion that appellant has "convey[ed] with reasonable clarity to those skilled in the art that, as of the filing date sought, [they were] in possession of the invention," <a href="Vas-Cath">Vas-Cath</a> (emphasis omitted). Accordingly, we reverse the rejection of claim 31 under the written description provision of 35 U.S.C. § 112, first paragraph.

# Enablement:

Claims 16 and 24-31 stand rejected under the enablement provision of 35 U.S.C. § 112, first paragraph.

## Claims 16 and 27-30

The examiner finds (Answer, page 36), claims 16 and 27-30

are broadly drawn to corn plants containing a multitude of exemplified or non-exemplified single gene conversions or transgenes of any sequence and from any source organism, wherein said single gene conversions or transgenes confer a multitude of exemplified or non-exemplified traits, and wherein said single gene conversions were introduced into the corn plant via

outcrossing with a multitude of non-exemplified corn plants containing the desired trait to be introduced....

In addition, the examiner finds (Answer, page 37), "[c]laim 16 ... implies that the male sterile corn plant simultaneously contains all of the genetic and morphological characteristics of I45046, which is in fact male fertile...."

According to the examiner (<u>id.</u>), "[n]o guidance has been provided for the isolation or characterization of a multitude of heterologous coding sequences ('transgenes') conferring a multitude of traits, as recited in claim 28." In addition the examiner finds (<u>id.</u>), "no guidance has been provided for <u>how to make</u> an 1450436 corn plant which is simultaneously male fertile and male sterile, as claimed in claim 16."

According to the examiner (Answer, page 40, emphasis added), "[i]it is not clear that single loci may be introduced into the genetic background of a plant through traditional breeding, while otherwise maintaining the genetic and morphological fidelity of the original inbred variety...."

With reference to Hunsperger, Kraft, and Eshed the examiner raises the issue of how linkage drag may hinder efforts to introduce a single gene into a plant by backcrossing, while recovering all of the original plant's genome.

Answer, pages 40-43.

We note, however, that claims 27-30 do not require that the single locus conversion plant <u>retain all of the morphological and physiological traits</u> of the parent plant in addition to exhibiting the single trait conferred by the introduction of the single loci. Nor do claims 27-30 require that the resultant plant retain all

of the original plant's <u>genome</u> in addition to the single locus transferred into the inbred <u>via</u> the backcrossing technique. As appellant explains (specification, bridging paragraph, page 30, emphasis added),

[t]he term single locus converted plant as used herein refers to those corn plants which are developed by a plant breeding technique called backcrossing wherein <u>essentially all</u> of the desired morphological and physiological characteristics of an inbred are recovered in addition to the single locus transferred into the inbred via the backcrossing technique.

See also appellant's definition of single locus converted (conversion) plant at page 23 of the specification. We find nothing in the appellant's specification to indicate that the single locus converted plant retains all of the morphological and physiological traits, or all of the genome, of the parent plant in addition to the single locus transferred via the backcrossing technique. The examiner provides no evidence that the converted plant exemplified in appellant's specification did not retain essentially all of the desired morphological and physiological characteristics of the inbred in addition to the characteristics conferred by the single locus transferred into the inbred via the backcrossing technique.

Claim 16, however, depends from claim 15 which does require the corn plant to be capable of expressing all the physiological and morphological characteristics of the corn variety I450436. We note, however, that appellant's specification discloses several means of conferring genetic male sterility that are available in the art. See e.g., bridging paragraph, pages 6-7 and pages 29-34. We find no evidence in the Answer to suggest this disclosure in appellant's specification is incorrect, or insufficient. In addition, we note that the examiner's

Appeal No. 2005-2266 Application No. 10/077,591

rejection of claim 6 is inconsistent with the manner in which a similar claim was treated in related applications 09/788,334 and 09/771,938, the subject matter of Appeal Nos. 2004-1506 and 2004-2317 respectively. Claim 16 of related applications 09/788,334 and 09/771,938, differs from claim 6 of the instant application only with regard to the corn variety. Nevertheless, while the disclosure in these related applications is substantially similar to the disclosure of the instant application, claim 16 was not rejected under the enablement provision of 35 U.S.C. § 112, first paragraph, in either of related applications 09/788,334 or 09/771,938.

Further, we recognize appellant's argument (Brief, page 25) that the examiner failed to establish a nexus between Hunsperger's discussion of petunias; Kraft's discussion of sugar beets; and Eshed's discussion of tomatoes, and the subject matter of the instant application - corn. Absent evidence to the contrary, we agree with appellant (id.), the examiner's opinion<sup>13</sup> that the references concerning petunias, sugar beets and tomatoes apply to corn is unsupported on this record. In this regard, we agree with appellant (id.), the examiner has improperly placed the burden on appellant to demonstrate that the examiner's unsupported assertion is not true. We remind the examiner, as set forth in In re Wright, 999 F.2d 1557, 1561-62, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993):

When rejecting a claim under the enablement requirement of section 112, the PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of

<sup>&</sup>lt;sup>13</sup> <u>See</u> Answer page 47, wherein the examiner asserts "[I]inkage drag appears to be a phenomenon that occurs in all plant types."

protection provided by that claim is not adequately enabled by the description of the invention provided in the specification of the application; this includes, of course, providing sufficient reasons for doubting any assertions in the specification as to the scope of enablement.

For the foregoing reasons, we reverse the rejection of claims 16 and 27-30 under the enablement provision of 35 U.S.C. § 112, first paragraph.

# Claims 24-26

Claims 24-26 ultimately depend from claim 23. On this record, the examiner has indicated that claim 23 is allowable. Answer, page 2. According to the examiner (Answer, page 37), claims 24-26 "are broadly drawn towards any hybrid corn [plant or] seed produced by the process of crossing the inbred corn plant 1450436 with any second, distinct, inbred corn plant...."

The examiner finds (Answer, page 38), "[n]o guidance has been provided regarding the morphological or genetic compositions of a multitude of non-exemplified breeding partners for crossing with 1450436...." According to the examiner this is true whether a single cross is preformed to produce a hybrid corn plant as claimed in claims 24-26, or multiple crosses with non-1450436 parents over multiple generations as claimed in claims 16 and 27-31.

The examiner interprets claims 24-26 as "drawn to a genus, i.e. any and all hybrid corn seeds, and ... plants produced by growing said hybrid seeds, wherein the hybrid seeds are produced by crossing inbred corn plant I450436 with any second, distinct inbred corn plant." See Answer, page 15. Accordingly, as we understand this record, see supra, n. 4, claims 24-26 are drawn to F<sub>1</sub>

hybrid seed and the plants produced by growing these seeds. The claims do not require the hybrid to express any particular morphological or physiological characteristic. Nor do the claims require that a particular non-I450436 corn variety be used. All that is required by the claims is that the F<sub>1</sub> hybrid has one parent that is a plant of corn variety I450436.

Since the examiner has indicated that the seed and the plant of the inbred line I450436 are allowable (see claims 1 and 5), there can be no doubt that the specification provides an adequate written description of this inbred corn line. In addition, the as appellant points out (Brief, page 26), appellant's "specification describes the creation of hybrid plant 8018717, which was produced with I450436 as one inbred parent," see e.g., specification, pages 53-59. Accordingly, it is unclear to this merits panel what additional enabling description is necessary. In our opinion, appellant's specification provides an enabling description of F<sub>1</sub> hybrids wherein one parent is a corn plant of the I450436 inbred line.

For the foregoing reasons, we reverse the rejection of claims 24-26 under the enablement provision of 35 U.S.C. § 112, first paragraph.

## Claim 31

As we understand the examiner's argument regarding claim 31, the claimed method may introduce unwanted genetic material, or dilute the I450436 genetic material. See e.g., page 43.

As we understand it, claim 31 is drawn to a method of using the I450436 inbred corn plant as the starting material to produce other inbred lines. In our opinion, it matters not what the other corn plants are, or what the progeny of a cross between the I450436 inbred line and some other corn plant represents. We emphasize that this claim is <u>not</u> drawn to a seed or plant that is the result of such a cross. The examiner has provided no evidence on this record that person of ordinary skill in the art could not produce another inbred line, using a corn plant of the I450436 inbred line as the starting material. Therefore, we are not persuaded by the examiner's unsupported assertions to the contrary.

For the foregoing reasons, we reverse the rejection of claim 31 under the enablement provision of 35 U.S.C. § 112, first paragraph.

## <u>SUMMARY</u>

We reverse the rejection of claims 3, 4, 6, 11, 15-17, 20, 27-30 under 35 U.S.C. § 112, second paragraph.

We reverse the rejection of claims 16 and 24-31 under the written description provision of 35 U.S.C. § 112, first paragraph.

We reverse the rejection of claims 16 and 24-31 under the enablement provision of 35 U.S.C. § 112, first paragraph.

# OTHER ISSUES

As discussed <u>supra</u>, n. 4, we understand claims 24 and 25 to refer to  $F_1$  hybrids. In this regard, we note that similar claims, directed to a different corn

variety, were presented for our review in Appeal Nos. 2004-1506 and 2004-2317. During the oral hearing in Appeal Nos. 2004-1506 and 2004-2317, appellant's representative confirmed that all claims drawn to hybrid plants or hybrid seeds (see e.g., claims 24 and 25) refer to F<sub>1</sub> hybrids. Further, based on our understanding of claim 25, claim 26 before us on appeal fails to further limit claim 25 from which it depends. Accordingly, prior to any further action on the merits, we encourage the examiner and appellant to work together to resolve this issue.

Toni R. Scheiner
Administrative Patent Judge

Donald E. Adams
Administrative Patent Judge

Administrative Patent Judge

Lora M. Green
Administrative Patent Judge

Administrative Patent Judge

Administrative Patent Judge

Administrative Patent Judge

Appeal No. 2005-2266 Application No. 10/077,591

FULBRIGHT & JAWORSKI L.L.P. A REGISTERED LIMITED LIABILITY PARTNERSHIP SUITE 2400 600 CONGRESS AVENUE AUSTIN TX 78701